Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Protocol summary

Study aim
The effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Design
Clinical practice with control and intervention group, with parallel groups, simple randomized triple blind

Settings and conduct
In this clinical trial study in Ninth Diabetes Hospital in 1397, each patient was enrolled by an anesthetist after an appointment and then examined for exit criteria. Then, the researcher will prescribe one of the two drugs based on the previously prepared randomized form and the nurse is not known to have any type of drug. For patients who are eligible, the pain questionnaire is filled up before and after 24 hours.

Participants/Inclusion and exclusion criteria
Entry Requirement: Satisfaction to participate in the study Subjected to cesarean section with spinal anesthesia No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them. Age 45-18 years Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases Conditions for not admitting to study: Performing a retinal anxiety Unwillingness to cooperate in the study General anesthesia Use of xanthine derivatives during the study

Intervention groups
Patients in both intervention and control groups randomly received aminophylline and normal serum saline (0.09%) and normal serum saline (0.09%).

Main outcome variables
Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: IRCT20180607040003N1
Registration date: 2018-09-03, 1397/06/12
Registration timing: retrospective

Last update: 2018-09-03, 1397/06/12
Update count: 0

Registration date
2018-09-03, 1397/06/12

Registrant information
Name
Hosein Bayesteh
Name of organization / entity
Iran (Islamic Republic of)
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+98 51 5224 3329
Email address
hosein_bayesteh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
2018-04-21, 1397/02/01
Actual recruitment end date
2018-04-21, 1397/02/01

Trial completion date
empty

Scientific title
Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Public title
Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section
anesthesia headache in women under cesarean section

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
- Satisfaction to participate in the study
- Subjected to cesarean section with spinal anesthesia
- No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them.
- Age 45-18 years
- Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases

**Exclusion criteria:**
- Performing a retinal anxiety
- Unwillingness to cooperate in the study
- General anesthesia
- Use of xanthine derivatives during the study

**Age**
From **18 years** old to **45 years** old

**Gender**
Female

**Phase**
1

**Groups that have been masked**
- Participant
- Care provider
- Outcome assessor

**Sample size**
- Target sample size: **70**
- Actual sample size reached: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Available sampling from all women candidates for cesarean section with spinal anesthesia referred to Razi Torbat Heydarieh Hospital and Allameh Bhol Gonabadi Hospital in Gonabad city, after being eligible for inclusion criteria by random allocation method using blocks Reversal, so that the number 1 as an intervention group (the group receiving aminophylline 3 mg based on the ideal body weight and 500 ml normal saline 0.9% venous) and the number 2 as the control group (receiving group 500 C C is considered to be 0.9% venous saline), and 4-block blocks (eg 2121) in the theme

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
In this study, the patients in the intervention group, after obtaining informed consent and entering the study, are not aware of which amniotic fluid injectable serum are available. Also, the clinical caregiver of the intervention group is unaware. Only the researcher has prepared the serum and the name of the patient in the intervention group and It will provide control to the clinical care provider for infusion, as well as assessing the outcome of the pain, the clinician will do without the knowledge of the intervention and control group.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**
- **Name of ethics committee**
  - Gonabad University of Medical Sciences
- **Street address**
  - Asian Roadside Border
- **City**
  - Gonabad
- **Province**
  - Razavi Khorasan
- **Postal code**
  - 9691793718
- **Approval date**
  - 2017-12-17, 1396/09/26
- **Ethics committee reference number**
  - IR.GMU. REC.1396.62

**Health conditions studied**

1

**Description of health condition studied**
- Headache

**ICD-10 code**
- G44

**ICD-10 code description**
- Other headache syndromes

**Primary outcomes**

1

**Description**
- Headache

**Timepoint**
- 24h

**Method of measurement**
- observation

**Secondary outcomes**
empty

**Intervention groups**

1

**Description**
- Intervention group: Headache before giving aminophylline in the aminofilin dose group. In this study, 3 cc per kg body weight of the drug are given at the diagnosis of the headache, and after an hour the patient
is examined by the doctor and the healing It is recorded.

**Category**
Treatment - Drugs

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**Description**
Control group: For patients in the control group, only 500 cc normal saline 0.9% intravenous infusion is infused over 2 hours.

**Category**
Treatment - Drugs

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**Recruitment centers**

1

**Recruitment center**

<table>
<thead>
<tr>
<th>Name of recruitment center</th>
<th>Women's Hospital, 9day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full name of responsible person</strong></td>
<td>hoseyn bayeste</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
<td>Razi Ave,Ferdowsi Blv</td>
</tr>
<tr>
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</tr>
<tr>
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<tr>
<td><strong>Postal code</strong></td>
<td>9516915169</td>
</tr>
<tr>
<td><strong>Phone</strong></td>
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</tr>
<tr>
<td><strong>Email</strong></td>
<td><a href="mailto:m.eshaghzadeh93@gmail.com">m.eshaghzadeh93@gmail.com</a></td>
</tr>
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**Sponsors / Funding sources**

1

**Sponsor**

<table>
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**Person responsible for general inquiries**

Contact

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**Person responsible for scientific inquiries**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available